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BY ECF & FEDERAL EXPRESS

Honorable Michael A. Hammer, U.S.M.J. Martin Luther King, Jr. Federal Building & U.S. Courthouse Court Room MLK 3C 50 Walnut Street Newark, New Jersey 07101

> Mylan Pharmaceuticals Inc. v. Celgene Corp. Re:

Civil Action No. 14-2094 (ES) (MAH)

Dear Judge Hammer:

Our firm, along with Wilson Sonsini Goodrich & Rosati, represents plaintiff Mylan Pharmaceuticals Inc. ("Mylan") in the above matter.

Pursuant to Local Civil Rule 37.1(a)(1) and paragraph 7 of Your Honor's Pretrial Scheduling Order (ECF No. 79), we write on behalf of Mylan and defendant Celgene Corporation ("Celgene") to submit this joint letter concerning a dispute that has arisen between the parties.

The parties jointly request an adjustment to the pretrial schedule entered by Your Honor. The parties agree that the August 6, 2015 date to produce documents responsive to written discovery (see id. ¶ 4) should be extended. However, an issue has arisen with respect to the length of such extension, as well as whether other deadlines in this matter should also be altered.1

By way of background, although the parties have produced documents and will continue to produce documents, they have both agreed that as a practical matter they will not be able to substantially produce all documents by the August 6 date as initially anticipated. This is due to the volume of documents responsive to each parties' requests that receiving parties have agreed to produce. Furthermore, there are a number of significant items in dispute that will affect the scope of the parties' respective document collections and productions; the parties plan to submit

¹ The parties have simultaneously exchanged the within submissions and have not had an opportunity to respond to the positions taken by the opposing party.

a joint letter on these items on August 12, 2015, in advance of the upcoming August 19, 2015 status conference with the Court. The parties will need additional time thereafter to review and produce any categories of documents ordered to be produced by Your Honor.

I. Plaintiff Mylan Pharmaceuticals Inc.'s Position

The parties agree that the August 6 deadline to produce responsive documents must be adjourned. Mylan proposes that the parties complete their production of documents not subject to privilege and/or redaction, and which are not the subject of pending disputes, by August 24; their production of redacted and/or privileged documents, as well as associated privilege and non-responsive redaction logs, and "throw backs," which are not the subject of pending disputes, by September 8; and their production of documents which are the subject of pending disputes, as well as associated privilege and non-responsive redaction logs, 45 days after the Court's Order requiring production of same.

In contrast, Celgene asserts that the Court should extend the deadline to produce non-disputed responsive documents until **September 30** – six weeks after Mylan's proposed deadline – and the deadline to produce documents subject to disputes to 60 days after the Court's ruling on them, rather than 45 days. Celgene has also demanded that the Court extend all remaining deadlines in this matter by approximately 45 days each. For the reasons explained herein, Mylan respectfully submits that, unlike Celgene's proposal, its suggested deadlines are pragmatic, do not result in unnecessary delays, and should be adopted by the Court.

Specifically, Celgene has taken what should be a relatively simple extension request and opportunistically requested extensions to *all* the deadlines in this case. First, Celgene has not indicated why it needs almost two additional months – and five total – to produce those non-disputed documents that have been requested since May 8, and Mylan submits that its proposal of an 18-day extension, providing the parties more than $3\frac{1}{2}$ months to produce documents, is sufficient.²

Second, and more egregiously, Celgene has not explained why it needs to extend *all* deadlines in this case by 45 days based on the slight delay in production of some, but not all, of the responsive documents in this matter. Even with an extension, the parties will have more than four months to complete deposition discovery, an entirely reasonable time period given the need to address the continuing irreparable harm caused by Celgene's conduct. Mylan respectfully submits that this time period, as well as those related to expert reports, could be compressed reasonably and without affecting the ultimate trial date in this matter.

² Likewise, Celgene has not indicated why it needs a full 60 days, rather than 45, to produce documents it has already known about for three months if Your Honor orders it to respond to certain requests in response to Mylan's forthcoming application to compel.

Celgene's proposal is antithetical to the schedule Your Honor set and the reasons therefore. As the Court is aware, access to the drugs that are the subject of this lawsuit is restricted, and Celgene has refused to permit (and continues to refuse to permit) Mylan access to these drugs, using its Risk Evaluation and Mitigation Strategies ("REMS") program as a pretext to prevent Mylan from acquiring the necessary samples to conduct bioequivalence studies required under the Hatch-Waxman Act, even after the FDA determined that Mylan's safety protocols were acceptable to conduct those studies. Mylan has alleged that that Celgene's refusal to provide samples was not motivated by safety concerns, but instead by a desire to prevent generic competition in order to maintain and extend its monopolies, that this refusal and thus harm is ongoing, and that it continues to cause irreparable injury to Mylan. Your Honor recognized this concern by setting a relatively aggressive discovery schedule – especially in an antitrust dispute such as this matter. Celgene's proposed extensions would only further compound this delay.

As indicated, Mylan believes that the following deadlines in lieu of the current August 6 deadline for the production of documents should be adopted by the Court:

- August 24, 2015: Deadline for the production of documents not subject to privilege and/or redaction, and which are not the subject of pending disputes
- September 8, 2015: Deadline for the production of redacted and/or privileged documents, as well as associated privilege and non-responsive redaction logs, and "throw backs," which are not the subject of pending disputes
- 45 days following the Court's ruling to produce documents which are the subject of pending disputes: Deadline for the production of documents, as well as associated privilege and non-responsive redaction logs

Mylan submits that these deadlines permit the parties sufficient time to complete their remaining obligations concerning document production. In contrast, Mylan respectfully submits that Celgene's proposed extension to multiple discovery deadlines (recounted above) are incongruent with the parties' need for an extension, and are instead an attempt to extend the harm caused by its own unlawful and anticompetitive behavior.

A proposed Order extending the document production deadlines as set forth herein is attached to this letter as Exhibit A for Your Honor's consideration. For the reasons set forth herein, Mylan respectfully requests that the Court grant the parties' joint request and enter Mylan's attached proposed Order.

II. Defendant Celgene Corporation's Position

Over the last several months, the parties have engaged in and served on each other written discovery and responses thereto, produced documents, and extensively met and conferred.

While the parties have agreed to serve written interrogatory responses and responses to requests for admission on August 6, the parties agree that substantial completion of document productions by August 6, 2015, is not feasible due to the massive document productions involved. Hence, the parties agreed to jointly request that the Court extend that deadline.

However, the parties disagree on the length of extension that is required. Celgene believes that an extension to September 30, 2015 is more realistic and feasible than the August 24, 2015 deadline that Mylan proposes. Thus far, Celgene has produced *over 350,000 documents* in response to Mylan's 74 document requests on a rolling basis, while Mylan has produced fewer than 1,000 documents. This imbalance demonstrates that Celgene is bearing a much greater share of the burden of producing documents. An extension of just over two weeks until August 24th is not sufficient time for Celgene to review the hundreds of thousands of documents still in the pipeline and complete its production.

Celgene has moved discovery along expeditiously through its substantial document production and numerous meet-and-confer efforts with Mylan counsel, all in the context of Mylan's expansive and broad discovery demands. No trial date has been set and the modest proposed extension of 45 days will not significantly delay resolution of this matter.

Therefore, Celgene respectfully requests that the Court amend the Pre-trial Scheduling Order as follows:

- Paragraph 3: Fact discovery is to remain open through February 26, 2016. No discovery is to be issued or engaged in beyond that date, except upon application and or good cause shown.
- Paragraph 4: Responses to document requests served to date as to which there is no dispute shall be completed on or before **September 30, 2015**. Responses to written discovery served to date as to which the parties have a dispute shall be completed **within 60 days** of the Court's ruling on the dispute.
- Paragraph 6: Fact depositions shall be completed by February 26, 2016.
- Paragraph 7: Discovery disputes regarding discovery requests served to date, other than those disputes relating to depositions, shall be brought to the Court's attention by **October 30, 2015**. Discovery disputes regarding subsequent, narrowly tailored discovery requests (referenced in Paragraph 2 of the

May 13, 2015 Amendment to Pretrial Scheduling Order), other than those disputes relating to depositions, shall be brought to the Court's attention by **January 30, 2016**.

Paragraph 17: All affirmative expert reports shall be served by April 24, 2016.

Paragraph 18: All responding expert reports shall be served by June 26, 2016.

Paragraph 19: All rebuttal expert reports shall be served by July 27, 2016.

Paragraph 20: All expert discovery, including the completion of expert depositions, shall be completed by **September 14, 2016**.

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The parties thank the Court for its consideration and assistance in these matters. Should the Court have any questions, the parties would be pleased to respond at the Court's convenience, or at the scheduled August 19, 2015 status conference before Your Honor.

Respectfully submitted,

Jakob B. Halp

/ibh

Attachment

cc: All counsel of record (by ECF & email)

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS INC.,
Plaintiff,

٧.

CELGENE CORPORATION,

Defendant.

Civil Action No. 14-2094 (ES) (MAH)

FIRST AMENDED PRETRIAL SCHEDULING ORDER

DOCUMENT FILED ELECTRONICALLY

THIS MATTER having been opened to the Court by Jakob B. Halpern, Esq., attorney for Plaintiff Mylan Pharmaceuticals Inc. ("Mylan"), by August 5, 2015 joint letter application on behalf of Mylan and defendant Celgene Corporation ("Celgene") for an Order amending the Pretrial Scheduling Order (ECF No. 79) with respect to certain deadlines therein; and the Court having considered the positions of Mylan and Celgene in such joint letter; and the Court having considered oral argument of the parties, if any; and the Court having considered the pleadings and status of this matter; and for the reasons expressed on the record; and for other and good cause having been shown,

IT IS on this _____ day of August, 2015, hereby

ORDERED the deadline to complete production of documents not subject to privilege and/or redaction, and which are not the subject of pending disputes, shall be adjourned to August 24, 2015; and it is further

ORDERED the deadline to complete production of redacted and/or privileged documents, as well as associated privilege and non-responsive redaction logs, and "throw backs," which are not the subject of pending disputes, shall be adjourned to September 8, 2015; and it is further

ORDERED the deadline to complete production of documents which are the subject of pending disputes, as well as associated privilege and non-responsive redaction logs, shall be

adjourned to forty-five (45) days following the Court's Order requiring production of same; and it is further

ORDERED that all other deadlines in the Pretrial Scheduling Order shall remain unchanged.

HONORABLE MICHAEL A. HAMMER UNITED STATES MAGISTRATE JUDGE